§170.315(f)(4) Transmission to cancer registries

2015 Edition CCGs

Version 1.2 Updated on 06-15-2020

Revision History

Version #	Description of Change	Version Date
1.0	Initial Publication	10-29-2015
1.1	Added clarification of update to allowable values for “Stager Clinical Cancer” and “Stager Pathologic Cancer” (also referred to as “Staged By”) data elements as the standard setters of the Implementation Guide for this criterion no longer require state cancer registries to collect “Stager Clinical Cancer” and “Stager Pathologic Cancer” data elements for cases diagnosed in 2018 or later.	05-31-2019
1.2	Updated the Security Requirements per 21st Century Cures Act.	06-15-2020

Regulation Text

Regulation Text

§170.315 (f)(4) *Transmission to cancer registries—*

Create cancer case information for electronic transmission in accordance with:

(i) The standard (and applicable implementation specifications) specified in §170.205(i)(2).

(ii) At a minimum, the versions of the standards specified in §170.207(a)(4) and (c)(3).

Standard(s) Referenced

Paragraph (f)(4)(i)

§ 170.205(i)(2) HL7 Implementation Guide for CDA© Release 2: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1, DSTU Release 1.1, April 2015

Paragraph (f)(4)(ii)

§ 170.207(a)(4) International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®), U.S. Edition, September 2015 Release

§ 170.207(c)(3) Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.52, Released June 2015, a universal code system for identifying laboratory and clinical observations produced by the Regenstrief Institute, Inc.

Certification Companion Guide: Transmission to cancer registries

This Certification Companion Guide (CCG) is an informative document designed to assist with health IT product development. The CCG is not a substitute for the 2015 Edition final regulation. It extracts key portions of the rule's preamble and includes subsequent clarifying interpretations. To access the full context of regulatory intent please consult the 2015 Edition final rule or other included regulatory reference. The CCG is for public use and should not be sold or redistributed.

Link to Final Rule Preamble

Edition Comparision	Gap Certification Eligible	Base EHR Definition	In Scope for CEHRT Definition
Revised	No	Not Included	Yes

Certification Requirements

Privacy and Security: This certification criterion was adopted at § 170.315(f)(4). As a result, an ONC-ACB must ensure that a product presented for certification to a § 170.315(f) "paragraph (f)" criterion includes the privacy and security criteria (adopted in § 170.315(d)) within the overall scope of the certificate issued to the product.

- The privacy and security criteria (adopted in § 170.315(d)) do not need to be explicitly tested with this specific paragraph (f) criterion unless it is the only criterion for which certification is requested.
- As a general rule, a product presented for certification only needs to be tested once to each applicable privacy and security criterion (adopted in § 170.315(d)) so long as the health IT developer attests that such privacy and security capabilities apply to the full scope of capabilities included in

the requested certification. However, exceptions exist for § 170.315(e)(1) "VDT" and (e)(2) "secure messaging," which are explicitly stated.
- § 170.315(d)(2)(i)(C) is not required if the scope of the Health IT Module does not have end-user device encryption features.

Table for Privacy and Security

- If choosing Approach 1:
  - Authentication, access control, and authorization (§ 170.315(d)(1))
  - Auditable events and tamper-resistance (§ 170.315(d)(2))
  - Audit reports (§ 170.315(d)(3))
  - End-user device encryption (§ 170.315(d)(7))
  - Encrypt authentication credentials (§ 170.315(d)(12))
  - Multi-factor authentication (MFA) (§ 170.315(d)(13))
- If choosing Approach 2:
  - For each applicable P&S certification criterion not certified for Approach 1, the health IT developer may certify using system documentation which is sufficiently detailed to enable integration such that the Health IT Module has implemented service interfaces the Health IT Module to access external services necessary to meet the requirements of the P&S certification criterion. Please see the *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program* Final Rule at 85 FR 25710 for additional clarification.

Design and Performance: The following design and performance certification criteria (adopted in § 170.315(g)) must also be certified in order for the product to be certified.
- When a single quality management system (QMS) is used, the QMS only needs to be identified once. Otherwise, the QMS' need to be identified for every capability to which it was applied.
- When a single accessibility-centered design standard is used, the standard only needs to be identified once. Otherwise, the accessibility-centered design standards need to be identified for every capability to which they were applied; or, alternatively the developer must state that no accessibility-centered design was used.

Table for Design and Performance

- Quality management system (§ 170.315(g)(4))
- Accessibility-centered design (§ 170.315(g)(5))

Technical Explanations and Clarifications

Applies to entire criterion

Clarifications:
- For the public health certification criteria in § 170.315(f), health IT will only need to be certified to those criteria that are required to meet the measures the provider intends to report on to meet Objective 8: Public Health and Clinical Data Registry Reporting.
- This certification criterion is intended for technology designed for the ambulatory setting.

- We have not adopted a “cancer case information” certification criterion. This decision has no impact on the requirements of the 2015 Edition “transmission to cancer registries” certification criterion or the requirements of the IG. Certification to the 2015 Edition “transmission to cancer registries” criterion requires a Health IT Module to demonstrate that it can create a file with the necessary cancer case information in accordance with the IG. [see also 80 FR 62667]
- “Cancer case information” is synonymous with the “cancer event reports” or “cancer reports” referred to in the HL7 Implementation Guide (IG) for CDA Release 2: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, DSTU Release 1.1.

Paragraph (f)(4)(i)

Technical outcome – The health IT can create cancer case information for electronic transmission in accordance with the HL7 IG for CDA Release 2: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, DSTU Release 1.1.

Clarifications:

- The CDC recently published an updated version of the Implementation Guide for reporting to cancer registries (HL7 IG for CDA® Release 2: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1; DSTU Release 1.1, U.S. Realm) (“Release 1.1.”). Release 1.1 involves technical corrections to Release 1. No new content has been included. We refer developers to the DSTU Release 1.1 for a full list of the updates. [see also 80 FR 62666]
- Mapping to the North American Association of Central Cancer Registries (NAACCR) format is not included in the IG because the mapping rules are complex, and can change over time based on continued input and refinement by the cancer registry community. It is our understanding that the CDC will work closely with the cancer registry community to develop mapping rules for the IG and will incorporate the rules into the software tools CDC provides state cancer registries. In regard to concerns expressed about jurisdictional variations, all public health jurisdictions have adopted the HL7 IG Release 1 for cancer reporting and will be moving to the updated version published by the CDC. [see also 80 FR 62666]
- Standard setters, the CDC National Program of Cancer Registries (NCPR), and the North American Association of Central Cancer Registries (NAACCR), no longer require state cancer registries to collect “Stager Clinical Cancer” and “Stager Pathologic Cancer” (also referred to as “Staged By”) data elements for cases diagnosed in 2018 or later. For testing of this criterion, we will allow for any valid value in the specified value set to be provided for the “Stager Clinical Cancer” and “Stager Pathologic Cancer” elements.

Paragraph (f)(4)(ii)

Technical outcome – The health IT can create cancer case information for electronic transmission using, at a minimum, the September 2015 Release of the U.S. Edition of SNOMED CT® and Version 2.52 of LOINC®.

Clarifications:

- We provide the following OIDs to assist developers in the proper identification and exchange of health information coded to certain vocabulary standards.
  - SNOMED CT® OID: 2.16.840.1.113883.6.96
  - LOINC® OID: 2.16.840.1.113883.6.1 [see also 80 FR 62612]
- Health IT Modules can present for certification to a more recent version of SNOMED CT®, U.S. Edition than the September 2015 Release and a more recent version of LOINC® than Version 2.52 per ONC’s policy that permits certification to a more recent version of certain vocabulary standards. [see also 80 FR 62620]

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